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December 20, 2019

VIA EMAIL

Adam M. Slater, Esquire
Mazie Slater Katz & Freeman, LLC
103 Eisenhower Parkway
Roseland, NJ 07068

Re: *In re Valsartan Products Liability Litigation*
Case No. 1:19-md-02875-RBK-JS

Dear Mr. Slater:

We write on behalf of Defendants in this litigation in response to your letter of October 25, 2019. In that letter, Plaintiffs ask a number of questions regarding Defendants' respective recall processes and the status of all valsartan in Defendants' possession. Plaintiffs also demand that each Defendant preserve "any valsartan API or finished dose products" in its possession, "whether or not they are subject to a recall [.]" As we read your request, any defendant would be required to retain and preserve any and all valsartan in, or that may pass through, its possession unless it is a "new product."

As we explain below, Defendants[1] have concerns regarding the intent and scope of Plaintiffs' directive, and hope that this response can help us reach an understanding on this issue. As should be clear by now, Defendants have been working and continue to work diligently and in good faith

[1] Given the nature of the shared concerns raised in this letter, and in the interest of facilitating a streamlined meet-and-confer process, all Defendants jointly raise these issues for Plaintiffs' consideration, and jointly object to the nature and scope of Plaintiffs' demand. Defendants make this collective attempt at a coordinated meet-and-confer process without prejudice to any Defendant's later right to meet and confer with Plaintiffs separately regarding any individual or unique concerns raised by Plaintiffs' October 25 letter.

to meet their discovery obligations under the Federal Rules of Civil Procedure. Defendants also have been working diligently to adhere to their federally-mandated responsibilities as manufacturers, distributors, re-packagers and pharmacies under and subject to the regulations of the U.S. Food and Drug Administration (the "FDA").

Plaintiffs' October 25 letter is in conflict with those FDA requirements insofar as it demands that Defendants deviate from established, existing drug recall procedures created with the input, assistance and approval of the FDA. Manufacturers of products under the purview of the FDA must follow FDA's regulatory scheme and guidance regarding product recalls, which direct that a recall notice should include "specific instructions on what should be done with respect to the recalled products."[2] Recall instructions are created with the guidance of FDA, and ultimately are subject to the agency's final review and approval. In conducting its review, the FDA reviews "the adequacy of a proposed recall strategy developed by a recalling firm and recommend changes as appropriate."[3]

The FDA directs recalling firms to conduct the recall in accordance with the approved recall strategy. These recall obligations do not stop with the company initiating the recall. Recipients of a recall notice, including downstream entities, also are directed to "immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to [their] consignees in accordance with paragraphs (b) and (c) of this section."[4]

In light of those regulatory requirements, Defendants object to the scope and substance of Plaintiffs' letter. Because each voluntary recall procedure instructs what manufacturers and downstream entities should do with recalled product, we anticipate that in many circumstances, retaining all recalled valsartan would violate these procedures. Accordingly, we are concerned that compliance with your request raises a conflict with applicable federal law, the purpose of which is to facilitate—not frustrate—FDA's ability to regulate pharmaceutical drugs in furtherance of the public health.[5] Any attempt to impose different, contrary or impeding requirements is preempted by the federal regulatory scheme.

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2 21 C.F.R. §7.49(c)(iv).

3 *Id.* at §7.42(a)(2).

4 *Id.* at §7.49(d).

5 U.S. Food and Drug Administration, *Guidance for Industry: Product Recalls, Including Removals and Corrections*, *available at* https://www.fda.gov/safety/industry-guidance-recalls/guidance-industry-product-recalls-including-removals-and-corrections ("[T]he cooperation of manufacturers and distributors in expediting recall activities is vital because of the determination that a distributed product is potentially hazardous to the

The scope and nature of Plaintiffs' demand also raise significant concerns regarding reasonableness and burden that are not in keeping with the directive under Federal Rule of Civil Procedure 26(b) that discovery be "proportional to the needs of the case" such that "the burden or expense of the proposed discovery [does not] outweigh[] its likely benefit."[6] Specifically, Plaintiffs' demand that each Defendant preserve each and every valsartan tablet, whether or not recalled, if implemented, would require each defendant to devote significant resources—in terms of manpower, finances *and* physical storage—in order to comply. Moreover, because Plaintiffs ask that each Defendant preserve every valsartan tablet in its possession, regardless of whether or not it is "returned" product, Plaintiffs' letter also can be read to demand that current and future distribution and sale of non-recalled valsartan tablets cease so that the product can be warehoused and preserved for Plaintiffs. That is something FDA itself has decided is not appropriate, and which could negatively affect patients' ability to access this important, life-saving medication across the country. In other words, the burden of complying with Plaintiffs' demand is substantial and carries significant consequences. It is unclear—particularly for non-recalled product—why any such effort is necessary or tailored to preserving the information you seek.[7]

Plaintiffs' October 25 letter imposes significant burdens on Defendants that directly conflict with and are an obstacle to the federal regulatory scheme concerning the recall of FDA-controlled products, and the sale and distribution of FDA-approved products that are not the subject of a recall. It also duplicates the substantial discovery already served on the Manufacturing Defendants, who have diligently worked for months to identify and produce core discovery to Plaintiffs.

For the reasons stated above, Defendants reject Plaintiffs' product preservation requests as framed, and they will continue to act pursuant to FDA guidance and regulation, and will continue to implement and follow the procedures for the handling of recalled product as approved by FDA. Defendants reject any attempt by Plaintiffs to impose any different, additional or conflicting obligations on them, or to interfere with the national drug supply chain for non-recalled product. We therefore cannot agree to the demands set forth in Plaintiffs' October 25 letter.

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public or animals and/or is in violation of the Federal Food, Drug, and Cosmetic Act (the Act).") (last updated Aug. 1, 2014).

6 Fed.R.Civ.P. 26(b)(1).

7 Defendants also note that Plaintiffs' letter cites CMO No. 1 (ECF 5) and Rule 37(e) as the basis for Plaintiffs' demand. Both the Court's order and Rule 37(e), however, refer to documents and electronic discovery, and as such do not apply to a request to maintain and store potentially millions of valsartan tablets, regardless of manufacturer, lot number or whether or not recalled. Moreover, even if applicable, both CMO No. 1 and Rule 37(e) invoke reasonableness standards, which are not met for the reasons set forth above.

Defendants submit these objections in good faith and welcome the opportunity to meet and confer further regarding these issues.

Very truly yours,

Seth A. Goldberg

SAG:dmr/DM1\10262928.1
cc: Plaintiffs' Executive Committee (**Via Email**)
Defendants' Executive Committee (**Via Email**)